Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

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Dockets Management Branch, HFA-305
Food & Drug Administration,
12410 Parklawn Drive
Rockville, MD 20857

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4 August 1997

SUBJECT: SAFETY MEASURES FOR EPHEDRINE DIETARY SUPPLEMENTS

To whom it may concern;

For the past 24 months, I have been using one product which contained both *ephedrine alkaloids* and high doses of *caffeine*. Per three tablets of the one product, would accumulate a dose of 334 mg's of *Mahuang Extract* (standardized 6%) and 910 mg's of *Gurana Extract* (standardized 22% caffeine). The manufacturers recommended daily dosage was to consume three tablets prior to breakfast, launch and dinner. However, I elected to take only six of the recommended nine tablets because I noticed sleep disturbance during the first month use of the manufacturers recommended dosage. Bringing the intake of ephedrine alkaloids to 668 mg's and the caffeine intake to 1820 mg's.

Let me begin by ruling out any mental health issues to the reader of this letter. I went through an extensive seven month psychological evaluation; conducted biweekly to have the clinical psychologist write the following diagnosis:

AXIS I: Personality change due to Neurological Disorder, Disinhibited Type
AXIS II: NONE
AXIS III: Probable degenerative neurological disorder, final diagnosis pending

In addition, a complete neuropsychological evaluation was performed, and summary read as follows: "Left hemisphere and frontal lobe dysfunction. Deficits most consistent with a progressive neurological disorder."

During the past 14 months have been going through an extensive neurological work-up to be characterized as having "*a progressive neurological disorder of unknown etiology.*" My chief medical complaints included, but not limited to the documented symptoms by competent medical authority are as follows: Seizures activity, headaches, tremors, fasciculation's all over the body, periodic leg movements, blurry vision, myclonous, cognitive deficits, sexual dysfunction and gastrointestinal problems.

Being stationed overseas in [redacted] with the US Army, a clear cause of my medical condition could not be pinpointed to a known disorder. An MRI was performed which reflected subcortical dementia and two EEG's showed no seizure platform but neurologist diagnosed seizure activity as being consistent with "complex partial seizures." I was referred last February 1997, to [redacted] for further evaluation of my medical condition.

While at [redacted] an EMG was performed that confirm the presence of benign fasciculation's, and myclonous. Additionally another MRI was performed but was without any additional finding's. A 48 hr video-EEG was conducted, again no seizure platform but confirmed myclonous and periodic leg movements.



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Upon discharge, the attending neurologist said my medical complaints represent a "*CHEMICAL IMBALANCE IN THE BRAIN*" and that no neurological disorders were detected. Having never mentioned my use of the herbal product that contain the above ingredients to any of the doctors during my the whole 14 month medical work-up; addressed it with that neurologist. It was felt it could be the culprit of my undiagnosed medical condition and was advised to discontinue the product.

I never mentioned the use of product, simply because I thought the ingredients were natural and therefore consider "*safe*." About a month after discontinuing the herbal product, a mark decline in the amount of fasciculation's my body would experience daily started to subside. The frequency of the seizure activity also diminished.

Upon extensive research of my medical complaints in relation to the potential dangerous ingredients found in the herbal product I was using, was able to narrow down to two known medical conditions that could possibly explain my medical complaints:

1) Oxidative Phosphorylation Dysregulation Syndrome (http://envprevhealthctratl.com/copds.html)
2) Eosinophilia-myalgia syndrome (EMS) without L-trytophan ingestion

I took my research to the military medical community and they never heard of the above conditions and did not want to look at them as possibilities. Even after the FDA 2 June 97 posting about the harmful effects of ephedrine alkaloids, they refuse to consider it! Despite lab test results that show elevated eosonophills on my lab results.

I think the FDA's proposal is a very good idea, consumers need to be made aware up front of the dangerous side affects of products by manufacturers that contain any ingredient that has the ability to impose significant health problems.

Should any member of the FDA wish to review the medical summaries, lab test, MRI films, etc. as cited in this letter, I will upon validation of a FDA members credentials released them. I have been spreading the word to anyone that I know about the FDA's 2 June 97 posting to try to prevent the harmful effects the ephedrine alkaloids have cause me.

Respectfully submitted,

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